Reliability of extracranial carotid artery duplex ultrasound scanning: Value of vascular laboratory accreditation

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Objectives: **The purpose of this study was to evaluate the reliability of carotid duplex ultrasound scanning performed by nonaccredited vascular laboratories and to assess the clinical effect on patient management.**

Methods: **We retrospectively reviewed concordance of findings of carotid duplex ultrasound scanning between laboratories accredited by the Intersocietal Commission for Accreditation of Vascular Laboratories and nonaccredited laboratories in 174 patients with asymptomatic disease referred to tertiary care community hospitals for surgical evaluation for carotid endarterectomy (CEA) between January 2001 and December 2002, and evaluated changes in clinical management made on the basis of repeat examinations.**

Results: **Concordant findings were noted in 171 of 348 arteries (49%), predominantly those with minimal or mild disease (114 arteries; 67%). Discordant findings of no clinical significance were found in 54 arteries (16%). Clinically significant discordant findings were noted in 123 arteries (35%) in 107 patients (61%). In 104 arteries (88 patients) stenosis was overestimated by the nonaccredited laboratory secondary to technical error (19 arteries), use of B-mode imaging data alone (36 arteries), and use of inappropriate velocity criteria (49 arteries). None of these patients underwent CEA. Stenosis was significantly underestimated in 19 arteries (19 patients); all of these patients underwent uncomplicated CEA.**

Conclusions: **Incorrect physician interpretation of data is the most common cause of error in carotid duplex ultrasound scanning performed in nonaccredited vascular laboratories. Results of carotid duplex ultrasound scanning from nonaccredited laboratories should be considered with extreme caution, and do not appear reliable in planning treatment of obstructive disease. (J Vasc Surg 2004;39:366-71.)**

The results of several multi-institution randomized trials provide a compelling rationale for surgical treatment of symptomatic and asymptomatic stenoses of the internal carotid artery (ICA) in appropriate patients on the basis of degree of stenosis.[1-3] While the evidence supporting surgical therapy for occlusive disease of the ICA is largely based on results obtained for treatment of angiographically confirmed stenoses, in modern clinical practice carotid duplex ultrasound scanning is increasingly the sole preoperative diagnostic study performed before carotid endarterectomy (CEA) in many medical centers.[4-6] Vascular surgeons have come to rely increasingly on the results of carotid duplex ultrasound scanning alone when making decisions regarding surgical intervention to treat carotid artery occlusive disease. The accuracy of carotid duplex ultrasound scanning in assessment of the degree of ICA stenosis is approximately 90% if performed with proper technique and interpreted by experienced clinicians with established and validated criteria.[7-9] However, the results of carotid duplex ultrasound scanning are both operator-dependent and technology-dependent.[10] Furthermore, not all vascular laboratories use identical criteria for determining degree of stenosis.[11-13] These discrepancies raise the possibility that interlaboratory variability in the diagnosis of ICA stenosis may have significant adverse effects on patient management and surgical decision-making.

The Intersocietal Commission for Accreditation of Vascular Laboratories (ICAVL) was established, in part, to ensure that the diagnostic results obtained from accredited vascular laboratories are both accurate and reproducible.[14] The establishment of standards for testing protocols, uniform criteria for determining degree of stenosis, and training and ongoing education of those technologists and physicians responsible for the studies serve to increase the reliability of carotid duplex ultrasound scans from ICAVL-accredited vascular laboratories. More than 1500 vascular laboratories in the United States have been accredited by ICAVL since 1990, but given the large number of carotid duplex ultrasound scanning examinations performed each year, a significant proportion clearly are done in nonaccredited vascular laboratories. A report by Elmore et al[15] showed poor concordance in terms of degree of stenosis between their accredited vascular laboratory and studies from outside vascular laboratories. In this study we report our findings on the concordance of carotid duplex ultrasound scanning performed in ICAVL-accredited versus

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Table I. Velocity criteria used to categorize stenosis greater than 60% diameter reduction

	PSV (cm/s)	*EDV (cm/s)*	*ICA/CCA*
Filis et al[12]	200	70	2.2
Moneta et al[11]	260/290	70/80	3.2/3.5
WBH*	250	90	3.5

PSV, Peak systolic velocity; *EDV,* end-diastolic velocity; *ICA/CCA,* internal carotid artery to common carotid artery PSV ratio.
*Internally validated data from quality assurance program.

nonaccredited vascular laboratories and the clinical implications of these findings on patient management.

MATERIAL AND METHODS

Records for patients with asymptomatic disease referred for surgical evaluation for CEA between January 2001 and December 2002 on the basis of findings on carotid duplex ultrasound scans from a nonaccredited vascular laboratory were reviewed. Absolute velocity and velocity ratio data (when included in the report) and interpretation of the outside studies were recorded. Clinical implications of each study were based on North American Symptomatic Carotid Endarterectomy Trial (NASCET) and Asymptomatic Carotid Atherosclerosis Study (ACAS) criteria for the treatment of carotid artery stenosis. All patients underwent repeat carotid duplex ultrasound scanning in an ICAVL-accredited laboratory. All repeat studies were performed by a registered vascular technologist. All studies were done using standardized testing protocols, with spectral Doppler velocity data and both longitudinal and transverse imaging of the extracranial carotid and vertebral arteries. Spectral Doppler velocity was obtained at an angle of insonation of 60 degrees or less, with attempts to be as close to 60 degrees as possible. Peak systolic velocity (PSV) and end-diastolic velocity of the ICA and distal common carotid artery, as well as the ICA-CCA PSV ratio, were recorded. In addition, the presence and direction of vertebral artery flow were recorded. Degree of stenosis was determined with the NASCET/ACAS method, with the diameter of the normal distal ICA serving as the reference, and the velocity criteria used were laboratory-specific data validated with internal quality assurance programs as mandated by the ICAVL (Table I). Patients whose treatment plan was altered on the basis of results of repeated carotid duplex scanning were noted. Data from any subsequent correlating imaging studies or surgeries were also recorded.

RESULTS

One hundred seventy-four patients were referred for surgical evaluation for CEA during the study. The interpretation and final reports from outside vascular laboratories were noted to contain no velocity data for 22 patients (13%); 69 reports (40%) contained only PSV data, with no end-diastolic velocity information; for 26 patients (15%) the ICA-CCA ratio was not calculated correctly; and the status of the vertebral arteries was not mentioned in 25 reports (14%). It was not possible to determine from the vast majority of reports whether the study had been performed by a registered vascular technologist, and the qualifications and training of the interpreting physician were not known.

Table II. Concordance of interpretations between ICAVL-accredited vascular laboratories and nonaccredited vascular laboratories (174 patients)

	n	*%*
Agreement	171/348 vessels	49
Minimal/mild disease	114/171 vessels	67
Minor discordance	54/348 vessels	16
Significant discordance	123/348 vessels	35
	107/174 patients	62
Stenosis overestimated	104/123 vessels 88 patients	51
Stenosis underestimated	19/123 vessels 19 patients	11

Table III. Causes for inaccurate estimation of stenosis (123 vessels)

	Overestimation (104 vessels)		*Understimation (19 vessels)*	
	n	*%*	*n*	*%*
Technical errors in velocity measurement	19	18	5	26
Use of B-mode imaging data only	36	35	7	37
Inappropriate velocity criteria	49	47	7	37

Agreement as to severity of carotid artery stenosis was found in 171 of 348 vessels (49%; Table II). One hundred fourteen (67%) of these stenoses were in vessels with minimal or mild disease contralateral to a vessel with diagnosed severe (>60% diameter reduction) or critical (>80% diameter reduction) stenosis, 45 were in vessels with severe or critical disease, and 12 were in totally occluded ICAs. Discordant findings were noted in 177 vessels. In 54 cases these discordant findings were minor, in vessels with minimal or mild disease, and not of any clinical significance. Clinically significant discordant findings, sufficient to alter patient management, were found in 123 arteries (35%) in 107 patients (61%).

In 104 vessels (88 patients) the study from a nonaccredited vascular laboratory overestimated the degree of stenosis, with a diagnosis of severe or critical disease; the repeat carotid duplex ultrasound scans showed these lesions to cause less than 60% diameter reduction (Table III). The overestimation of the degree of stenosis was a result of technical errors in velocity measurement in 19 arteries (18%), estimation of the degree of stenosis based on B-mode images and not velocity criteria in 36 arteries (35%), and use of diagnostic criteria different from the NASCET/

ACAS method in 49 arteries (47%). None of these patients underwent CEA. Two patients underwent follow-up magnetic resonance angiography (MRA), which confirmed the ICAVL-accredited laboratory findings; the remainder of patients continue to have no symptoms, and are scheduled for noninvasive follow-up appropriate to their findings.

In 19 arteries (19 patients) disease severity was significantly underestimated at the original duplex ultrasound scanning examination (Table III). In these patients underestimation of degree of stenosis was a result of technical error in velocity measurement in 5 vessels (26%), use of B-mode image data alone to determine the degree of stenosis in 7 vessels (37%), and applyication of non-NASCET/ACAS criteria in 7 vessels (37%). MRA images confirmed the ICAVL laboratory findings in 5 of these patients, and all 19 patients underwent successful CEA without complication, with confirmation of significant carotid artery atherosclerotic disease at surgery.

DISCUSSION

The benefits of CEA in patients with symptomatic disease with greater than 50% arteriographically confirmed stenosis of the ICA and in patients with asymptomatic disease with greater than 60% stenosis are well-established.[1-3] Carotid angiography was accepted as the gold standard for assessment of degree of stenosis in these studies. However, carotid angiography is an invasive diagnostic procedure associated with 0.2% to 4% risk for serious complications, including approximately 1% risk for stroke.[1,2] Moreover, it has been estimated that carotid angiography may be seven to ten times more costly than duplex ultrasound scanning for the preoperative evaluation of carotid artery occlusive disease.[7] In the past two decades carotid duplex ultrasound scanning increasingly has become the noninvasive diagnostic procedure of choice for the preoperative evaluation of stenoses involving the extracranial ICA.[4-6,8] In experienced centers duplex ultrasound scanning is highly sensitive and specific, making it preferable as a screening test in patients with suspected extracranial carotid artery occlusive disease. This popularity has resulted in a steady expansion and proliferation of noninvasive vascular laboratories, from primarily hospital-based facilities to freestanding diagnostic centers, private medical offices, and mobile diagnostic units. In this context of an expanding market for noninvasive vascular testing, an unfortunate result may be that economic considerations and the widespread availability of noninvasive vascular technology have become important engines driving the proliferation. In such an economic environment there exists the risk that cost-effectiveness, diagnostic accuracy, and clinical efficacy may decline, to the detriment of clinical outcome and overall quality of patient care. In response to such increasing concerns, the ICAVL was established in 1990, with the mission of providing a peer review mechanism to ensure high-quality patient care by setting appropriate standards for noninvasive vascular testing.

The evidence supporting CEA for the treatment of extracranial ICA occlusive disease is based on the degree of stenosis as determined at carotid arteriography. Given the increasingly widespread clinical acceptance of the results of carotid duplex ultrasound scanning as a sole preoperative diagnostic study, it is absolutely essential that surgical decision-making be based on findings of noninvasive studies performed with accurate technique and on appropriate interpretation with validated criteria. Technical factors leading to inaccurate results include poor patient positioning, inappropriate transducer selection, poor optimization of instrument gain and display settings, and, likely most important, incorrect spectral Doppler technique when measuring blood flow velocity. In this study technical errors resulted in a clinically significant inaccurate velocity estimation in 24 arteries, 19% of the vessels with significant discordance.

Anatomic factors such as severe calcification, anomalies such as kinks or coils in the ICA, and contralateral ICA occlusion may produce flow disturbances, leading to errors in Doppler scanning velocity analysis. Abou-Zamzam et al[16] reported that contralateral carotid artery stenosis can have a significant effect on ipsilateral ICA flow velocity, leading to the inaccurate impression of significant stenosis. In this study lack of recognition of one or more of these factors in a small number of patients also was noted to lead to overestimation of the severity of disease present.

In addition to technical factors, improper interpretation of the data obtained and the use of velocity criteria that were not validated with a quality assurance mechanism led to significantly inaccurate results. Errors were noted in the interpretation of data from 43 vessels in which B-mode imaging data, not velocity information, were used as the primary determinant of stenosis. The great majority of these errors (36 arteries, 84%) resulted in significant overestimation of the severity of stenosis, not a surprising result of this practice. While B-mode imaging is reliable in demonstrating minimal or mild obstructive disease, as disease severity increases the accuracy of imaging alone significantly decreases to a sensitivity of less than 50%, and accurate velocity data are required to stratify lesions.[17,18] The most frequent cause of error in the studies done in nonaccredited vascular laboratories was the use of clinically inappropriate velocity criteria that had not been validated with some mechanism of quality assurance, such as correlation with angiography. The beneficial effect of CEA found in the NASCET and ACAS studies was based on using the disease-free distal ICA as the reference vessel to define percent stenosis, not the previously used carotid bulb diameter. This "new" definition of stenosis has led to a number of published reports listing velocity criteria for diameter reduction greater than 50%, 60%, and 70%, criteria that are dramatically different, for example, from those originally published by Langlois et al[19] for which the carotid bulb was the reference vessel diameter (Table I). In the present study there appeared to be 49 arteries in which velocity was measured correctly but the degree of stenosis was significantly overestimated by a nonaccredited vascular laboratory; the velocity recorded did not even closely approximate any of the criteria in Table I or other references

for the degree of stenosis given in the final impression. These errors in "overreading" by the nonaccredited vascular laboratories were not secondary to disagreement in velocity data, but to lack of knowledge or understanding regarding the accepted criteria for defining degree of stenosis. These results are consistent with those reported by Elmore et al,[15] who demonstrated that more than 60% of patients referred on the basis of findings of outside duplex ultrasound scanning and initially classified as having high-grade stenosis (80%-99%) were inaccurately classified. Without having gone through the accreditation process and meeting the mandated quality assurance standards, nonaccredited vascular laboratories have not availed themselves of any mechanism of self-review that would demonstrate the errors in interpretation.

Data from Filis et al[12] suggest that clinical management of carotid artery stenosis can be successfully based solely on findings at carotid duplex ultrasound scanning in 97% of patients, given that the studies were performed in their ICAVL-accredited laboratory. The results of the present study suggest that a similar algorithm may not be appropriate for studies performed in nonaccredited vascular laboratories. In the present study, of the 174 patients referred for surgical evaluation for CEA, 88 patients (51%) were found to have less than the 60% or greater stenosis diagnosed by a nonaccredited vascular laboratory. These patients were spared the potential consequences of unnecessary CEA. In an additional 19 patients with less than 60% diameter stenosis diagnosed by a nonaccredited vascular laboratory, a repeat study in an accredited vascular laboratory showed greater than 60% diameter stenosis in one ICA. All 19 of these patients underwent uncomplicated CEA, which provided them with a statistically significant chance of decreasing their risk for stroke, an opportunity these patients likely would not have had if carotid duplex ultrasound scanning had not been repeated and the degree of stenosis accurately determined.

In light of these findings we have adopted a policy to repeat all carotid duplex ultrasound scanning that has been performed by a nonaccredited laboratory. However, the inaccuracies of vascular laboratories that are not accredited then also lead to a financial dilemma. With the data provided by Axelrod et al[20] for this study in a single institution over 2 years, an additional $32,190 was spent to repeat carotid duplex ultrasound scanning in these patients. Projected nationwide, these costs would easily exceed several million dollars per year. However, most insurance carriers will not provide reimbursement for such a repeated study, forcing the accredited vascular laboratory to absorb this cost. This financial burden, coupled with the increasing number of nonaccredited practices performing carotid duplex ultrasound scanning, may make repeating these examinations cost-prohibitive. With an inaccuracy rate of greater than 60% for nonaccredited vascular laboratories, patients and the physicians to whom they are referred may be put in the position of using more costly confirmatory studies such as MRA or cerebral angiography.

In conclusion, carotid duplex ultrasound scanning has become the sole preoperative diagnostic study in an increasing number of patients before CEA. The noninvasive nature and diagnostic accuracy of carotid duplex ultrasound scanning, when performed in an ICAVL-accredited vascular laboratory, would seem to justify this practice paradigm in a substantial majority of patients. On the other hand, the results of this study suggest that interpretation of carotid duplex ultrasound scans by nonaccredited vascular laboratories should be considered with extreme caution. Our results demonstrate that inaccurate determination of the degree of stenosis by nonaccredited vascular laboratories may adversely affect patient management and surgical decision-making in approximately 60% of patients. The necessity of having to repeat these studies produces an unnecessary strain on financial resources, and, if confirmed prospectively in larger series, the results of this preliminary study raise the important question of whether the continued reimbursement of studies performed in nonaccredited vascular laboratories is justified.

REFERENCES

1. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. N Engl J Med 1991;325:445-53.
2. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. JAMA 1995;273:1421-8.
3. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. N Engl J Med 1998;339:1415-25.
4. Ranger WR, Glover JL, Bendick PJ. Carotid endarterectomy based on preoperative duplex ultrasound. Am Surg 1995;61:548-54.
5. Gertler JP, Cambria RP, Kistler JP, Geller SC, MacDonald NR, Brewster DC, et al. Carotid surgery without angiography: noninvasive selection of patients. Ann Vasc Surg 1991;5:253-6.
6. Collier PE. Changing trends in the use of preoperative carotid arteriography: the community experience. Cardiovasc Surg 1998;6:485-9.
7. Dawson DL, Zierler RE, Strandness DE Jr, Clowes AW, Kohler TR. The role of duplex scanning and arteriography before carotid endarterectomy: a prospective study. J Vasc Surg 1993;18:673-80.
8. Khaw KT. Does carotid duplex imaging render angiography redundant before carotid endarterectomy? Br J Radiol 1997;70:235-8.
9. Huston J, James EM, Brown RD Jr, Lefsrud RD, Ilstrup DM, Robertson EF, et al. Redefined duplex ultrasonographic criteria for diagnosis of carotid artery stenosis. Mayo Clin Proc 2000;75:1133-40.
10. Fillinger MF, Baker RJ Jr, Zwolak RM, Musson A, Lenz JE, Mott J, et al. Carotid duplex criteria for a 60% or greater angiographic stenosis: variation according to equipment. J Vasc Surg 1996;24:856-64.
11. Moneta GL, Edwards JM, Papanicolaou G, Hatsukami T, Taylor LM Jr, Strandness DE Jr, et al. Screening for asymptomatic internal carotid artery stenosis: duplex criteria for discriminating 60% to 99% stenosis. J Vasc Surg 1995;21:989-94.
12. Filis KA, Arko FR, Johnson BL, Pipinos II, Harris EJ, Olcott C, et al. Duplex ultrasound criteria for defining the severity of carotid stenosis. Ann Vasc Surg 2002;16:413-21.
13. Moneta GL, Edwards JM, Chitwood RW, Taylor LM Jr, Lee RW, Cummings CA, et al. Correlation on North American Symptomatic Carotid Endarterectomy Trial (NASCET) angiographic definition of 70% to 99% internal carotid artery stenosis with duplex scanning. J Vasc Surg 1993;17:152-7.
14. Kempczinski RF, Thiele BL, Strandness DE, Bandyk DF. Accreditation of vascular laboratories. J Vasc Surg 1990;12:629-30.

15. Elmore JR, Franklin DP, Thomas DD, Youkey JR. Carotid endarterectomy: the mandate for high quality duplex. Ann Vasc Surg 1998;12: 156-62.
16. Abou-Zamzam AM Jr, Moneta GL, Edwards JM, Yeager RA, Taylor LM Jr, Porter JM. Is a single preoperative duplex scan sufficient for planning bilateral carotid endarterectomy? J Vasc Surg 2000;31:282-8.
17. Comerota AJ, Cranley JJ, Cook SE. Real-time B-mode carotid imaging in diagnosis of cerebrovascular disease. Surgery 1981;89:718-29.
18. Comerota AJ, Cranley JJ, Katz ML, Cook SE, Sippel PJ, Hayden WG, et al. Real-time B-mode carotid imaging: a three year multicenter experience. J Vasc Surg 1984;1:84-95.
19. Langlois Y, Roederer GO, Chan A, Phillips DJ, Beach KW, Martin D, et al. Evaluating carotid artery disease: the concordance between pulsed Doppler/spectrum analysis and angiography. Ultrasound Med Biol 1983;9:51-63.
20. Axelrod DA, Diwan A, Stanley JC, Jacobs LA, Henke PK, Greenfield LJ, et al. Cost of routine screening for carotid and lower extremity occlusive disease in patients with abdominal aortic aneurysms. J Vasc Surg 2002;35:754-8.

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DISCUSSION

Dr Enrico Ascher (Brooklyn, NY). I rise to congratulate the authors for a timely study that reproduces what many of us have noted in our practices.

Dr. Brown, just for clarification, are the non-ICAVL-accredited laboratories also not accredited by the American College of Radiologists or the American Institute of Ultrasound in Medicine? While I agree with most of your conclusions, I believe that, to be even more persuasive, your study should have included a comparison of results with another ICAVL-accredited laboratory.

In your protocol, and also in ours, we included routine insonation of the vertebral arteries. Could you comment on the value of this approach, since in our experience we have found very little value for this approach. Because of the dramatic improvement in the quality of B-mode imaging, we now rely more and more on these measurements than on velocities. It is possible that some of the discrepant results in your study may have been caused by differences between hemodynamic and B-mode imaging results. As you know, low peak systolic velocities can be reflective of long 99% stenosis in the ICA, and high peak systolic velocities can be created by vessel tortuosity. Since oscillations in systemic blood pressures and cardiac output can influence velocity measurements, could these have accounted in part for the differences in results?

Dr. Brown, many of us will not operate routinely on 60% stenoses. Could you tell us about the accuracy of outside laboratories for carotid lesions causing 80% or greater stenosis.

Last, what's your protocol to detect pseudoaneurysms of the ICA?

I enjoyed reading the manuscript and listening to your presentation.

Dr O. William Brown. Thank you very much for your comments, Dr. Ascher. Let me try to go through these one at a time here, if I can.

As far as the other accreditations, I do not know whether the other laboratories were or were not accredited by other organizations.

As for the vertebral arteries, we agree that evaluation of the vertebral arteries probably does not provide additional information in asymptomatic patients. However, evaluation of the vertebral arteries may be very beneficial in patients who have nonhemispheric or atypical cerebral symptoms. Therefore we continue to include vertebral artery evaluation as part of our protocol.

As you know, the problem with using B-mode imaging techniques is that the degree of stenosis tends to be overestimated by individuals who are not familiar with looking at these types of images.

We, too, do not operate on all patients with greater than 60% stenosis. However, 60% was felt to be the most consistent end point, as opposed to attempting to factor in each individual surgeon's philosophies.

I, unfortunately, can't tell you exactly how many were 80% to 90%. In some of the reports that we reviewed the stenosis read from 50% to 90%, 70% to 85%, making a breakdown of the number of 80% to 90% lesions impossible.

Dr R. Eugene Zierler (Seattle, Wash). I am serving as one of the AAVS representatives to the ICAVL board, and I am also the current president of the ICAVL, so nobody in this room is more pleased with the results of your study than I am. However, I do have some concerns. If I understand correctly, you actually looked at one nonaccredited lab and one accredited lab. So I would ask how generalizable you think your conclusions may be with regard to a larger number of labs? That's my first question.

My second comment and question concerns the qualifications of the technologist or sonographer. You tended to focus on the interpreting physicians, and you were unable to tell us whether the nonaccredited lab had credentialed sonographers. In many regions, the third-party payers now require either credentialed sonographers or an accredited lab in order to qualify for reimbursement. Therefore you may find that you could get reimbursed for your repeat studies if the lab that performed the initial study did not meet either of these criteria.

Dr Brown. As for your first question, there were multiple nonaccredited laboratories. These were nonaccredited laboratories from several areas. There was only one accredited laboratory.

Obviously, in a retrospective preliminary study such as this one, I'm not sure just how generalizable our findings will be. However, like others, we found this to be a continuing problem.

Dr Munier Nazzal (Toledo, Ohio). Dr. Brown, I have two questions.

The first one: Most probably you based your interpretation of other hospitals or labs on written reports. Did you look at films, videotapes, or the whole study, or not?

The second question: Your version of interpretation and theirs, what they were compared with, is it angiogram or just your interpretation?

Dr Brown. We did not review the actual studies. Some of the nonaccredited laboratories are unwilling to provide their studies for review.

We used our ICAVL lab as baseline.

Dr Daniel J. Reddy (Detroit, Mich). We have had a parallel experience with other labs within our own system. In our practice a primary care doctor, for example, may have sent the patient to a more conveniently located lab and then referred the patient to us for study confirmation and advice. What we notice about the first test is that, along with the occasional misinterpretation is an often inappropriate suggestion to get an altogether different study, such as an arteriogram. How often in your study did the initial screening lab study result carry with it advice to get an arteriogram or other study that may have been avoided by a diagnostic quality rather than screening quality study?

Dr Brown. Most of the time the outside laboratories do suggest that angiography be performed in any patient with even a minor degree of stenosis.

Dr Gregory L. Moneta (Portland, Ore). We need to move away from this concept of identifying a specific level of stenosis. Every individual and every combination of duplex-derived flow parameters is associated with a different combination of sensitivity and specificity for identifying or excluding the presence of a specified level of angiographic stenosis. Every combination of sensitivity and specificity is associated with different positive and negative predictive values. When the intention is to identify patients for a possible prophylactic operation and the therapeutic index of the operation is narrow, as it is for endarterectomy for asymptomatic carotid stenosis, you don't want to have parameters that just identify a level of stenosis with high sensitivity; you also want to be able to identify that category of stenosis with a very high positive predictive value. So my question is, what positive predictive value was associated with your criteria for a 60% lesion?

Dr Brown. I think that our predictive value, in that case, was 97% or 98% predictive value.

INVITED COMMENTARY

R. Eugene Zierler, MD, *Seattle, Wash*

The primary conclusion of this study by Brown et al— that the results of carotid duplex scanning performed in non-accredited vascular laboratories are less reliable than those from Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL)–accredited laboratories—should not surprise anyone who has taken on the arduous task of accrediting their own laboratory. But what does accreditation mean? Laboratories that have successfully completed the ICAVL accreditation process in one or more of the five testing areas are in compliance with a comprehensive set of standards that have been set by a multidisciplinary commission of physicians and sonographers. These standards cover all aspects of vascular laboratory practice, from instrumentation, testing protocols, interpretation criteria, and reporting to the experience and training of personnel and quality assurance programs. Ongoing compliance with ICAVL standards is documented with periodic reaccreditation, including relevant continuing education for both medical and technical staff.

While the results reported here are intuitively satisfying and clear, the study has some limitations that must be acknowledged. First, the study was retrospective and based solely on the content of the final reports from the non-accredited laboratories. Original B-mode or color-flow images and Doppler waveforms were not available; therefore it is not possible to critically assess how the tests were actually performed. In addition, the qualifications of the sonographers and physicians in the non-accredited laboratories were not known. Finally, the study involved a large number of non-accredited laboratories, but only a few accredited laboratories. Consequently there are a multitude of variables that may account for the observed differences in outcome, many of which are linked in some way to laboratory accreditation.

Carotid scanning is the most standardized and straightforward duplex examination performed in the vascular laboratory. If the conclusions of this study are accepted, it would be reasonable to assume that similar (or even more extreme) differences between non-accredited and accredited laboratories would be found for the other applications of duplex ultrasound scanning. Physicians and patients, who are the "consumers" of vascular laboratory services, are entitled to some assurance that accurate and reliable testing is being performed. Accreditation of laboratories and credentialing of sonographers are two mechanisms for demonstrating that diagnostic testing is being done in a manner that meets at least minimum standards. The value of these processes is supported in that an increasing number of states (about 26, at this writing) have linked payment for vascular laboratory testing to either accreditation or credentialing. This report by Brown et al should serve to focus attention on the issue of accreditation and strengthen this trend.